

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Comparative evaluation of sequential therapy versus triple therapy and concomitant four-drug therapy for eradication of helicobacter pylori infection in children from 5 to 15 years old

#### Protocol summary

##### Summary

The aim of this study is to compare the evaluation of sequential therapy versus triple therapy and concomitant four drug therapy for eradication of Helicobacter pylori infection in children with gastrointestinal disorders. Inclusion criteria will be included: patients with digestive disorders such as recurrent abdominal pain; gastrointestinal bleeding and dyspepsia. Exclusion criteria will be included: having a history of taking medications such as antibiotics; bismuth; proton pump inhibitors; Histamine receptor antagonists and non steroid anti inflammatory drugs in the last 4 weeks. The study population will be included all children from 5 to 15 years old with gastrointestinal disorders. The sample size will be 120 patients. Intervention and its time will be included: treatment in group A with Omeprazole plus Amoxicillin plus Clarithromycin over 10 days, treatment in group B with Omeprazole plus Amoxicillin in the first 5 days and then Omeprazole plus Metronidazole plus Clarithromycin over the next 5 days and treatment in group C with Omeprazole plus Amoxicillin plus Clarithromycin plus Metronidazole over 10 days. The primary outcome variables will be included: Helicobacter pylori in the corpus specimen, Histopathology of stomach biopsy, Helicobacter pylori in anther sample, rapid urease test and Helicobacter pylori stool antigen.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2017062234698N1**

Registration date: **2017-09-06, 1396/06/15**

Registration timing: **prospective**

Last update:

Update count: **0**

##### Registration date

2017-09-06, 1396/06/15

##### Registrant information

###### Name

Behrooz Kamani

###### Name of organization / entity

Qazvin University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 28 3332 8709

###### Email address

b.kamani@qums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Qazvin University of Medical Sciences

##### Expected recruitment start date

2017-09-23, 1396/07/01

##### Expected recruitment end date

2019-02-20, 1397/12/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Comparative evaluation of sequential therapy versus triple therapy and concomitant four-drug therapy for eradication of helicobacter pylori infection in children from 5 to 15 years old

##### Public title

Drug therapy of Helicobacter pylori infection

##### Purpose

Treatment

### **Inclusion/Exclusion criteria**

Inclusion criteria: patients with digestive disorders such as recurrent abdominal pain; gastrointestinal bleeding and dyspepsia. Exclusion criteria: having a history of taking medications such as antibiotics; bismuth; proton pump inhibitors; Histamine receptor antagonists and non steroid anti inflammatory drugs in the last 4 weeks.

### **Age**

From **5 years** old to **15 years** old

### **Gender**

Both

### **Phase**

N/A

### **Groups that have been masked**

*No information*

### **Sample size**

Target sample size: **120**

### **Randomization (investigator's opinion)**

Randomized

### **Randomization description**

### **Blinding (investigator's opinion)**

Not blinded

### **Blinding description**

### **Placebo**

Not used

### **Assignment**

Factorial

### **Other design features**

## **Secondary Ids**

empty

## **Ethics committees**

### 1

#### **Ethics committee**

##### **Name of ethics committee**

Qazvin University of Medical Sciences

##### **Street address**

Shahid Bahonar Blvd., Qazvin

##### **City**

Qazvin

##### **Postal code**

59811-34197

##### **Approval date**

2017-06-21, 1396/03/31

##### **Ethics committee reference number**

IR.QUMS.REC.1396.118

## **Health conditions studied**

### 1

#### **Description of health condition studied**

Helicobacter pylori infection

#### **ICD-10 code**

B98.0

#### **ICD-10 code description**

Helicobacter pylori [H.pylori] as the cause of diseases classified to other chapters

## **Primary outcomes**

### 1

#### **Description**

Helicobacter pylori in the corpus specimen

#### **Timepoint**

Four weeks after the last day of treatment

#### **Method of measurement**

Standard protocol

### 2

#### **Description**

Histopathology of stomach biopsy

#### **Timepoint**

Four weeks after the last day of treatment

#### **Method of measurement**

Standard protocol

### 3

#### **Description**

Helicobacter pylori in another sample

#### **Timepoint**

Four weeks after the last day of treatment

#### **Method of measurement**

Standard protocol

### 4

#### **Description**

Rapid urease test

#### **Timepoint**

Four weeks after the last day of treatment

#### **Method of measurement**

Standard protocol

### 5

#### **Description**

Helicobacter pylori stool antigen

#### **Timepoint**

Four weeks after the last day of treatment

#### **Method of measurement**

Standard protocol

## **Secondary outcomes**

### 1

#### **Description**

Body mass index

#### **Timepoint**

Four weeks after the last day of treatment

#### **Method of measurement**

Body mass index formula

## Intervention groups

### 1

#### Description

Group A: Omeprazole plus Amoxicillin plus Clarithromycin over ten days

#### Category

Treatment - Drugs

### 2

#### Description

Group B: Omeprazole plus Amoxicillin in the first five days and then Omeprazole plus Metronidazole plus Clarithromycin over the next five days

#### Category

Treatment - Drugs

### 3

#### Description

Group C: Omeprazole plus Amoxicillin plus Clarithromycin plus Metronidazole over ten days

#### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Quds Hospital

##### Full name of responsible person

Behrooz Kamani

##### Street address

Quds Hospital, Quds Square, Shahid Beheshti Blvd., Qazvin

##### City

Qazvin

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Qazvin University of Medical Sciences

##### Full name of responsible person

Amir Peymani

##### Street address

Qazvin University of Medical Sciences, Shahid Bahonar Blvd., Qazvin

##### City

Qazvin

##### Grant name

##### Grant code / Reference number

##### Is the source of funding the same sponsor organization/entity?

Yes

##### Title of funding source

Qazvin University of Medical Sciences

##### Proportion provided by this source

100

##### Public or private sector

empty

##### Domestic or foreign origin

empty

##### Category of foreign source of funding

empty

##### Country of origin

##### Type of organization providing the funding

empty

## Person responsible for general inquiries

#### Contact

##### Name of organization / entity

Qazvin University of Medical Sciences

##### Full name of responsible person

Rita Baqerian

##### Position

Postdoctoral

##### Other areas of specialty/work

##### Street address

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md.yar88@yahoo.com

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<http://hosgods.qums.ac.ir/Portal>

## Person responsible for scientific inquiries

#### Contact

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Amaneh Barikani

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M.D.

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**Position**

General Physician

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**Sharing plan**

**Deidentified Individual Participant Data Set (IPD)**

*empty*

**Study Protocol**

*empty*

**Statistical Analysis Plan**

*empty*

**Informed Consent Form**

*empty*

**Clinical Study Report**

*empty*

**Analytic Code**

*empty*

**Data Dictionary**

*empty*